



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Biftu, et al.
Serial No.: 10/556,805
Docket No.: 21404P
Filed: November 14, 2005
For: 3-AMINO-4-PHENYLBUTANOIC ACID DERIVATIVES
AS DIPEPTIDYL PEPTIDASE INHIBITORS FOR THE
TREATMENT OR PREVENTION OF DIABETES

Art Unit: 1624

Examiner:
Brenda Coleman

Mail Stop Issue Fee
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPLICATION FOR RECONSIDERATION OF PATENT TERM
ADJUSTMENT UNDER 37 C.F.R. §1.705(b)

Sir:

This is a request for reconsideration of the patent term adjustment (PTA) indicated in the Notice of Allowance mailed January 15, 2009. This application is being submitted under 35 CFR §1.705 with the payment of the issue fee.

Applicants request that the PTA determination be corrected to include the days accrued pursuant to 37 CFR 1.702(b). The Patent Office delay under 1.702(b) is occurring more than three years after the subject application was filed and does not overlap with the 612 days due to delay under 37 CFR 1.702(a).

According to 37 CFR 1.702(a)(1), the term of an original patent shall be adjusted if the issuance of the patent was delayed due to the failure of the Office to mail at least one of a notification under 35 U.S.C. 132 or a notice of allowance under 35 U.S.C. 151 not later than fourteen months after the date on which the application fulfilled the requirements of 35 U.S.C. 371 in an international application. The requirements under section 371 for this international application were fulfilled on November 14, 2005. The date fourteen months after the section 371 requirements were fulfilled is January 14, 2007. A first office action was mailed on September

17, 2008, which constitutes 612 days of Patent Office delay under 37 CFR 1.703(a); i.e., the number of days from January 14, 2007 to September 17, 2008.

There were no circumstances constituting a failure of Applicants to engage in reasonable efforts to conclude processing or examination of the application as set forth in 37 CFR 1.704. Accordingly, the PTA accrued under 37 CFR 1.702(a)(1) is PTO Delay – Applicant Delay = 612 – 0 = 612 days.

According to 37 CFR 1.702(b), the term of the original patent shall be adjusted if the issuance of the patent was delayed due to the failure of the Office to issue a patent within three years after the date on which the national stage commenced under 35 U.S.C. 371. The date three years after commencement of the national stage is November 14, 2008. According to 37 CFR 1.703(b), the number of days accrued to date under Rule 1.702(b) is 151 days; i.e., the number of days from November 14, 2008 to April 14, 2009. The final determination cannot be made until an issue date for the patent is set.

There has been no delay due to Applicants during the 1.703(b) period. Accordingly, as of today Applicants are entitled to $612 + 151 = 763$ days of PTA.

The PTA determination of the Patent Office (copy attached hereto as Exhibit 1) lists 612 days of Patent Office delay and 0 days of Applicant delay. The Patent Office PTA determination does not include the delay due to the failure to issue the patent within three years of the commencement of the national stage. The rationale for this omission is that the Patent Office has considered the delay under 37 CFR 1.702(a)(1) and 1.702(b) to be overlapping such that an applicant is entitled to the delay due to either 1.702(a)(1) or 1.702(b), whichever is longer, but not both. Reference is made, however, to Wyeth v. Dudas, Civil Action No. 07-1492 (JR), 2008 U.S. Dist. LEXIS 76063 (DC, September 30, 2008) ("Wyeth"; copy attached hereto as Exhibit 2). The Wyeth case presents essentially the same factual situation as presented in the instant application. In Wyeth, the plaintiff argued that the time period due to actual Patent Office delay and the time period due to failure of the Office to issue the patent within 3 years of the filing date do not overlap unless there is actual overlap. The Court agreed, stating that, for purposes of determining PTA, the "only way that periods of time can 'overlap' is if they occur on the same day." Applying the Wyeth precedent to the instant situation, there is no actual overlap between the 612 days of Patent Office delay and the 151 days (and counting) due to failure to

issue a patent within three years. Accordingly, Applicants are entitled to the sum of the days arising from the two sources of delay.

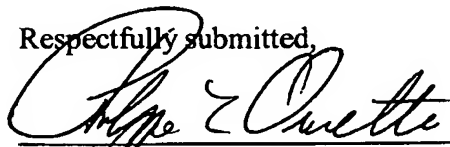
It is further noted that the patent that issues from the subject application will not be subject to a terminal disclaimer.

Accordingly, it is requested that the PTA determination for this application be changed to add the delay due to the Patent Office failure to issue a patent within 3 years to the earlier accrued 612 days of PTA.

The Commissioner is authorized to charge the fee set forth in § 1.18(e) to Deposit Account No. 13-2755.

Respectfully submitted,

By:



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Date: April 14, 2009

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on the date appearing below.

MERCK & CO., INC.

By Pamela Spalding Date 4-14-09